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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 875,519	06/06/2001	Timothy C. Farnes	4-30443B D1	6920

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EXAMINER

DECLoux, AMY M

ART UNIT PAPER NUMBER

1644

DATE MAILED 01/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/875,519

Applicant(s)

FARRIES ET AL.

Examiner

Amy M. DeCloux

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 05 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 1,37 and 51-56 is/are pending in the application.
- 4a) Of the above claim(s) 1, 37, 51-54 and 56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 06 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/142,334.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 and 11
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group VII, claim 55, in Paper No. 10, filed 11-5-02, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1, 37 and <sup>51-54 + 56</sup>~~51-56~~ have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.
3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### *Specification*

The disclosure is objected to because of the following informalities: the pages are not consecutively numbered, for example there are four page "22"s. Also there is no "Table II", though there are two different tables labeled "Table I". Appropriate correction is required.

### *Information Disclosure Statement*

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered. Specifically, the list of references on pages 69-70 of the instant specification has not been considered.

The IDS filed 8-20-01 (Paper No. 7) is acknowledged and has been considered. The IDS filed 11-5-02 (Paper No. 11) is also acknowledged. However, since all the references listed on the 1449 form filed with the IDS filed 11-5-02 (Paper No. 11), were listed on the 1449 form filed with the IDS filed 8-20-01 (Paper No. 7), the later dated IDS has not been considered.

*Claim Rejections - 35 USC § 112*

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 55 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA sequence encoding a modified human C3 protein with one or more of the following mutations: E992S, D993A, D996S, A997Q, E998S, R999G, L1000M, K1001N, H1002I, V1005H, Q1152R, E1153K, K1155F, R954E, the double mutant R954Q + E955G, REA1591-3 stop or frame shift, does not reasonably provide enablement for a DNA sequence encoding a modified human C3 protein with any mutations in the region defined by amino acid residues 992-1005, 1546-1663, 954, and/or 955 of native human C3 (SEQ ID NO:22).

The specification does not enable any person skilled in the art to which it pertains, or with which it is most clearly connected, to make and use the invention commensurate in scope with these claims.

Claim 55 is drawn to a DNA sequence encoding a modified human C3 protein which is capable of forming a stable C3 convertase, wherein said modified protein is a C3 protein comprising one or more mutations in the region defined by amino acid residues 992-1005, 1546-1663, 954, and/or 955 of native human C3 (SEQ ID NO:22), said protein having reduced susceptibility to Factor H and/or Factor I, relative to native human C3.

The instant specification discloses DNA sequences which encode modified human C3 proteins having reduced susceptibility to Factor H and/or Factor I, relative to native human C3, which is capable of forming a stable C3 convertase, comprising one or more of mutations E992S, D993A, D996S, A997Q, E998S, R999G, L1000M, K1001N, H1002I, V1005H, Q1152R, E1153K, K1155F, R954E, the double mutant R954Q + E955G, REA1591-3stop or frame shift.

Farries et al teach in a post filing date reference (Xenotransplantation (1998) 5:29-34) the first such recombinant mutant (see entire article, including page 29, column 2). Therefore, in light of the state of the art at the time the invention was made, it would require undue experimentation for one of skill in the art to predict which mutations in the recited regions would produce a C3 protein with the recited properties without further guidance and direction from the specification. The problem of predicting polypeptide structure and function of any of the innumerable mutations in human C3 recited by the instant claims that confer resistance or reduced susceptibility to Factor H and/or Factor I is complex and well outside the realm of routine experimentation. This complexity is due

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in part to the fact that the relationship between the amino acid sequence of a peptide (and its corresponding encoding nucleic acid sequence) and its tertiary structure (i.e. its activity) are not well understood and are not predictable (e.g. see Ngo et al., (V), newly cited, in The Protein Folding Problem and Tertiary Structure Prediction, 1994, Merz et al., (ed.), Birkhauser, Boston, MA, pp. 433 and 492-495). In re Fisher, 166 USPQ 18 indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. The specification does not provide sufficient enablement for a DNA sequence encoding a modified human C3 protein which is capable of forming a stable C3 convertase, wherein said modified proteins is a C3 protein comprising any one or more mutations in the region defined by amino acid residues 992-1005, 1546-1663, 954, and/or 955 of native human C3 (SEQ ID NO:22), said protein having reduced susceptibility to Factor H and/or Factor I, relative to native human C3, other than the mutations of human C3 protein stated above.

In view of the quantity of experimentation necessary, the limited working examples, the unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, it would take undue experimentation to practice the claimed invention.

### *Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy M. DeCloux whose telephone number is 703 306-5821. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 703 308-3973. The fax phone numbers for the organization where this application or proceeding is assigned are 703 872-9306 for regular communications and 703 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308-0196.

Amy DeCloux, Ph.D.  
Patent Examiner,  
Group 1640  
January 27, 2003

*Amy M. DeCloux*  
*1-27-03*